

**REMARKS/ARGUMENTS**

***Status of the Claims***

Upon entry of this amendment, claims 1-6, 9-10, 13-16, and 18-22 are pending in this application and are presented for examination. Claim 22 has been amended to set forth proper dependency from claim 10. No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

***Formalities***

In the Advisory Action, the Examiner alleged that Applicants did not provide the publication date of Exhibit A from the response dated April 11, 2005. In response, Applicants respectfully draw the Examiner's attention to the phrase "64 FR 56681 (10/21/99)" from the penultimate line of Exhibit A, which refers to the publication of the disclosure in Volume 64 of the Federal Register at page 56681 on October 21, 1999. As such, Applicants respectfully request that Exhibit A be considered.

***Rejection under 35 U.S.C. § 103(a)***

The Examiner has maintained the rejection of claims 1-6, 8-10, and 12-16 as allegedly being obvious over the combination of U.S. Patent 5,866,152 ("the '152 patent"), PCT Publication No. WO 87/04617 ("the '617 publication"), and U.S. Patent 6,207,694 ("the '694 patent").

The Examiner alleges that it would have been obvious to prepare the compositions of the '152 patent by increasing the concentration of PEG to greater than 20% and combining it with an antifungal agent for the control of dermal infection (*see, page 3 of the Office Action mailed December 10, 2004*). According to the Examiner, the motivation to use higher concentrations of PEG stems from the teaching of the '617 publication that higher concentrations of PEG can dissolve the active ingredients so that better fungicidal properties are exhibited and that PEG also acts as a penetration enhancer (*see, id*).

Applicants assert that the response dated April 11, 2005, which is incorporated herein by reference, overcomes the Examiner's *prima facie* obviousness rejection because there

is simply no reason to apply the disclosures of the '617 publication and the '694 patent regarding formulations for treating hyperkeratotic skin conditions (*i.e.*, fungal infections) to modify the formulations of the '152 patent, which were developed for the disparate purpose of controlling ectoparasites such as lice. However, even if the Examiner maintains the rejection in view of the response dated April 11, 2005, Applicants believe that the submission herewith of a Declaration of Mr. Albert Zorko Abram under 37 C.F.R. § 1.132 ("the Declaration"), which presents objective evidence of unexpected results over the cited art, is sufficient to rebut the Examiner's *prima facie* obviousness rejection.

As set forth in M.P.E.P. § 716.02(a):

Presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

As explained by Mr. Abram in the Declaration, the present invention possesses unexpected advantageous properties *not present* in the closest cited art. In particular, Mr. Abram describes a side-by-side comparative experiment in which the inventive formulation of Example 1 (Sample A) was compared to the formulation of Example 3 from the '152 patent manufactured according to the method disclosed in the '152 patent (Sample B) or using an order of addition of the various components that matched more closely with the inventive formulation (Sample C) (*see*, paragraph 6 of the Declaration). Surprisingly, Sample A showed no signs of particulates or crystals over a period of 7 days at any of the storage temperatures tested (*see*, paragraph 7 of the Declaration). In contrast, Samples B and C had a 1 to 2 mm layer of crystalline material that had settled to the bottom of the glass jar at all temperatures tested (*see*, paragraphs 8-9 of the Declaration). According to Mr. Abram, the results of this 7 day study showed that clotrimazole remained in solution with the inventive formulation of Example 1 (Sample A) but not with Example 3 from the '152 patent, regardless of how it was prepared (Samples B & C) (*see*, paragraph 10 of the Declaration).

Based upon this comparative study, Mr. Abram declares that the formulation of Example 3 from the '152 patent was not able to produce a stable single-phase liquid shampoo (*see*, paragraph 12 of the Declaration). In particular, clotrimazole failed to dissolve in any

version of Example 3 prepared according to the method disclosed in the '152 patent (Sample B) (*see, id*). Although clotrimazole did initially dissolve in another version of Example 3 prepared according to the method disclosed in the present application (Sample C), some crystalline material accumulated within 24 hours of storage (*see, id*). As a result, this study demonstrates that the inventive formulation remains as a single-phase liquid shampoo following the initial preparation (*see, paragraph 13 of the Declaration*). In contrast, the comparative formulation was not able to produce a stable single-phase, crystal-free liquid, regardless of the manufacturing technique (*see, id*). Thus, Mr. Abram concludes that the inventive formulation remains homogeneous during dispersing, whereas the comparative examples do not provide a consistent homogeneous dose of the formulation (*see, paragraph 14 of the Declaration*). For the foregoing reasons, it is Mr. Abram's scientific opinion that the present invention possesses unexpected advantageous properties ***not present*** in the cited art (*see, paragraph 15 of the Declaration*).

In view of the foregoing, Applicants believe that the present showing of unexpected results over the cited art is sufficient to rebut the Examiner's *prima facie* obviousness rejection. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Appl. No. 10/069,448  
Amdt. dated August 12, 2005  
Reply to Advisory Action of April 29, 2005

PATENT

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

  
Joseph R. Snyder  
Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
Attachments  
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